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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,535	10/30/2003	David T. Curiel	678503-2001.1	7880

7590 10/14/2008  
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745 Fifth Avenue  
New York, NY 10151

EXAMINER
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EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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10/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/697,535

**Applicant(s)**

CURIEL ET AL.

**Examiner**

Janet L. Epps-Ford

**Art Unit**

1633

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6-30-08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25, 27-32, 34-44 and 47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43 and 44 is/are allowed.
- 6) ☒ Claim(s) 25, 27-32, 34-42 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112***

2. Claims 25, 27-32, 34-42, and 47 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. Applicant's arguments filed 6-30-08 have been fully considered but they are not persuasive. Applicant's traversed the instant rejection on the grounds that the claims, herewith and as originally presented, are in full compliance with the requirements of 35 USC 112. Particularly, Applicants argued that the instant rejection should be reconsidered and withdrawn since the specification as filed, particular at paragraphs [0182]-[0183] provide support for the presently amended claims. Moreover, Applicants argue that the amendment to the claims to indicate that the "deletion of nucleotides 324 to 488" of the adenoviral subtype 5 genome "from a pAdEasy-1 vector," demonstrates that Applicants had possession of the claimed invention, And thus the rejection should be withdrawn.

4. Contrary to Applicant's assertions, there is no support for the present amendment to instant claim 25 and 34, since there is no explicit disclosure which states

that the pAdEasy-1 vector comprises the full adenoviral subtype 5-genome. Thus, it is not clear that the nucleotide sequence of nucleotides 324 to 488 recited in the instant claims, correspond to the same nucleotide sequence as the region of nucleotides 324 to 488 of the pAdEasy-1 vector. Therefore, the nucleotide sequence composition which corresponds to the limitation "nucleotides 324 to 488" of the adenoviral subtype 5 genome remains unclear.

As stated in the prior Office Action, claim 25 combines the deletion of nucleotides 324 to 488 with the limitation that the tumor-specific promoter is operably linked to the E1 early gene. Example 13 and Fig. 23 only describe replacing nucleotides 324 to 488 with the tumor-specific promoter, e.g. VEGF promoter. As was previously stated, even where the promoter is operably linked to E1 (as now amended), there is no clear support for inserting the tumor-specific promoter anywhere but in place of the deleted nucleotides 324 to 488. However, the instant claims do not require that the VEGF promoter is inserted in the region wherein nucleotides 324 to 488 were deleted.

Furthermore, since the instant claims are not limited to a specific sequence which defines the nucleotide structure, it is unclear which nucleotides the nucleotides 324 to 488 correspond to. Therefore, the limitation in claim 25 may also be construed to mean that the Ad5 genome has a deletion of from 324 nucleotides to 488 nucleotides at any unspecified location. The limitations in claims 25 and 34 may also be construed to mean that the Ad5 genome has a deletion in the region of its nucleotides 324 to 488 (as now recited in the instant claims). See rejection under 35 USC 112, second para. below. However, to the extent that the claims as now amended do not reflect that the deletion

corresponding to nucleotides 324 to 488 correspond to the Ad5 genome, and wherein the deletion is in the region of the E1A promoter, the claims now suggest that the deletion of nucleotides 324 to 488 in the Ad5 genome does not necessarily require that the deletion be in the region of the E1A promoter.

Consequently, there is no evidence from the original specification that Applicant had contemplated or possessed this genus as broadly as it is claimed.

5. The rejection of claim 43 under 35 U.S.C. 112, first paragraph, is withdrawn in response to Applicant's amendment.
6. Claims 25, 27-32, 34-42, and 47 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. As stated in the prior Office Action, Applicants have amended the instant claims to recite: "a deletion of nucleotides 324 to 488 of the adenoviral subtype 5 genome." Moreover, Applicants have presently amended the instant claims to recite wherein the adenoviral subtype 5 genome from a pAdEasy-1 vector. Contrary to Applicant's assertions, since there is no apparent standard for numbering the adenoviral subtype 5 genome from a pAdEasy-1 vector, as recited in the instant claims, it is unclear which nucleotides the range of 324 to 488 are referring to, since the claims are not limited to any particular nucleotide sequence such that one of ordinary skill in the art could clearly distinguish which nucleotides Applicants are referring to.

8. Applicants are reminded of the following statement set forth in the 2<sup>nd</sup> ¶ of prior Office Action:

9. The rejections under 35 USC 102 and 103 and for double patenting (*set forth in the Non-final Action of 11/20/2006*) are withdrawn due to the amendments of claims 25 and 34 requiring the deletion of nucleotides 324 to 488 of the Ad5 genome. However, as indicated below these limitations in their present form are indefinite and include new matter. Should the limitations be deleted, rather than revised, reinstatement of the withdrawn rejections may be necessary.

**Conclusion**

10. Claims 43-44 are allowable over the prior art.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/  
Primary Examiner, Art Unit 1633

JLE